Mass production of disposable syringes

Demanding mould project combines mould making and hotrunner competence

Active cavity shut-off

Increased production reliability for complex multi-cavity moulds

EWIKON service area enlarged

New technical centre
When producing disposable syringes highest precision in mould making is required to guarantee the perfect function of the finished product. Werkzeugbau Ruhla GmbH in Seebach, Germany now has successfully entered this demanding business segment by building 10 full hotrunner multi-cavity moulds for disposable syringes with filling volumes from 1 ml up to 20 ml. The close cooperation with EWIKON ensured that during this project mould making and hotrunner expertise complemented each other in an ideal way.

The customer runs a modern, automated production plant for medical components in Russia and is a supplier to the Russian Federation as well as to the international market. The new mould project was started to further increase the productivity and the efficiency when producing disposable syringes with filling volumes of 1 ml, 2 ml, 5 ml, 10 ml and 20 ml according to the medical DIN EN ISO 7886 standard. The total production capacity is 375 millions of syringes per year. When working with the Werkzeugbau Ruhla GmbH the customer benefits from the company’s long-term expertise in the production of injection moulds for medical applications as well as from the profound knowledge of the Eastern European markets with a considerable sales volume there.

However, designing and building moulds for syringes was a new challenge for
the company. "Moulds for the syringe production have their own special requirements", explains Udo Köllner, technical director at Ruhla, "they must be built with particularly high dimensional precision with special focus on optimal cooling of the mould inserts as well as on even filling of the cavities. The latter is important to eliminate deflection of the inner cores by the melt pressure and thus to avoid ovality caused by uneven wall thickness of the syringe barrel. All this especially applies to two-piece syringes as produced with the new moulds." Two-piece syringes do not feature an additional plunger seal made of a soft component which - due to elastic deformation - can compensate inaccuracies in production. "Even dimensional deviations of 2/100 of a millimetre are enough to cause problems with leak tightness and the required force to push the plunger and thus can affect the functionality to such an extent that the finished syringe is reject", says Köllner, for this reason we have invested in a special measuring and testing machine especially for this project. Now we can check these parameters inhouse during the pre-production tests and refinish mould components when necessary. Considering the high production volume direct gating with a full hotrunner solution was the method of choice to optimise cycle times, save material and avoid subsequent work steps. Each syringe size requires two moulds, one for the PP barrel and one for the plunger which is made of PE. The mould design is based on the planned production volume for the respective version. This resulted in 48 cavities for the most frequently used 2 ml and 5 ml versions, 32 cavities for the 10 ml version, 24 cavities for the 1 ml version and 16 cavities for the 20 ml version. Barrel and plunger are both gated from the side in a 90° angle to the demoulding direction. The shear action during demoulding is used to achieve a perfect surface quality without gate marks which, for several reasons, are not acceptable for the medical industry.

Considering the long-term successful cooperation in side gating Ruhla decided to go for EWIKON hotrunner technology. "When we have to realise a project of this scale within a very tight time frame we cannot afford to take any risk when it comes to technical solutions.

A special testing machine checks the proper function of the finished syringes during the pre-production tests.
So we have to fully trust in our supplier”, says Köllner, “after all we are talking of total mould costs of more than 2 million Euros with a share of more than 500,000 Euros for the hotrunner technology. And up to now our experiences with EWIKON side gating solutions have been positive without exception.” EWIKON supplied the hotrunner technology for all moulds as a complete package consisting of the hot half and the matching touch screen control system. For the production of barrels and plungers different radial and linear versions of the HPS III-MH side gating nozzles are used. The syringe barrels are positioned in the mould in demoulding direction and are arranged in compact circles, each one with a radial nozzle in the centre. Depending on the size four or eight barrels are gated simultaneously with one nozzle. The heat conductive tips are angled by 60°. Thus, the gating point can be positioned as closely as possible to the parting line and the mounting of the inner core so that core displacement caused by the melt pressure is minimised. In the moulds for the plungers the parts lie in the parting line at right angle to the demoulding direction. A slide mechanism is integrated to prevent the parting line from running across the sealing front plate of the plunger and therefore to eliminate the risk of flashing in this sensitive area. All plunger moulds feature linear nozzles. This design allows to arrange the plungers in a row and enables an easy and cost-effective integration of the slide mechanism. The gating point is placed on the plunger head. On the manifold side all moulds are equipped with the HPS III-T technology which uses streamlined direction elements for a fully balanced melt distribution to the nozzles. Since the flow channel layout inside the nozzles is balanced as well, an even filling of all cavities is guaranteed.

During each stage of the mould project Ruhla and EWIKON worked in close cooperation with the customer. Moldflow analyses for each version of the syringe were conducted in order to check and - if necessary - optimise the article design with regard to the injection moulding process. Important parameters were the wall thicknesses of the barrels as well as the design of the plungers where necks in the rear area of the plunger rod help to save material. Furthermore, when starting the project 8-drop test moulds for barrels and plungers of the 1 ml and 5 ml version were built within a very short time to determine the optimum dimensions for important mould components. The results were directly incorporated in the design of the production moulds. Thus, the expenditure of time in this project stage could be considerably reduced.
Precision mould making is the core competence of Werkzeugbau Ruhla GmbH. All components are manufactured by using state-of-the-art machinery. One of the highlights is a fully automated manufacturing cell for electrodes which has reduced the production time by 70% and increased the sinker EDM capacity by 30%. A further advantage is the highly motivated team. “Many of our employees have worked in the watchmaking industry”, Köllner points out, “and thus have an increased awareness of quality and precision. The company really benefits from that.” All moulds have a very compact, modular and easy-to-maintain design. “The mould inserts are easily exchangeable if required”, explains Udo Köllner, “and the other mould components have been designed with focus on utmost maintainability as well. The EWIKON side gating systems allow to quickly exchange the tip inserts from the parting line without having to dismantle the mould from the machine. And in case a nozzle itself needs maintenance we have installed them in a separate mould plate which also has the wiring integrated. So the whole nozzle unit can be completely separated from the manifold plate with minimum effort. In general EWIKON could supply a tailored hotrunner solution for each syringe size and the respective mould design.” A most compact design for the mould and the hotrunner system was important because the customer plant is equipped with fully electric injection moulding machines. The machine size used only allows a certain mould weight. For this reason Ruhla had to reduce the weight of the larger moulds. This was done by placing additional cutouts in thoroughly calculated positions so that the mould stability was not affected.

To guarantee an efficient production with high repeatability Ruhla paid special attention to effective mould venting and cooling. The former is important to ensure proper filling of the cavities especially for the thin walled syringe barrels and thus to avoid reject caused by incomplete filling or air entrapments. In the moulds for the syringe barrels a special cooling concept has been implemented. It allows a cooling layout which surrounds the whole cavity in a close distance although the part is gated from the side. This was feasible because a particularly slim version of the EWIKON HPS III-MH nozzle is used here which has been especially designed for the production of syringes and pipettes. Furthermore, Ruhla managed to integrate cooling for the inner core even for the smallest barrel size. The results were cycle times below ten seconds for all syringe sizes.

After all designs have been approved by the customer the whole project including extensive pre-production tests for each mould in the Ruhla technical centre and checking of the finished parts could be realised in 28 weeks only. When the moulds went into serial production Ruhla and EWIKON application engineers supported the customer on-site to ensure a trouble-free system startup and to conduct final adjustments to the production parameters.

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For production of the syringe barrels the HPS III-MH111 nozzle is used. Its particularly slim design leaves enough space in the mould inserts to integrate surrounding cooling close to each cavity.
Active cavity shut-off avoids production downtimes

When using multi-cavity hotrunner systems in complex multi-component or insert-moulding applications cavity failures such as broken cores and faulty ejectors or cooling can cause unexpected production downtimes. For moulds equipped with a pneumatic valve gate system EWIKON now offers a new technology which allows the active shut-off of single cavities. Thus, regardless of broken cavities the production can be continued for example until a certain order quantity has been moulded.
The new technology was developed for use with valve gate drive units which are integrated in the clamping plate. The cavity shut-off is realised by permanently closing the respective valve pin and decreasing the nozzle temperature at the same time. To enable this the air supply is different compared to conventional systems. Normally the clamping plate contains a layout of bores that supplies several drives simultaneously with compressed air. The EWIKON technology features a separate, balanced air supply for each drive which is integrated in an additional compact mould plate placed behind the clamping plate. The compressed air is fed "horizontally" into the drive supply bores. In addition to all supply lines the plate contains a newly developed valve technology. For each drive unit the supply lines for valve pin opening and closing have special valves integrated. To shut off a cavity the supply line for valve pin opening is closed with the first valve and thus made pressureless. In the next step the second valve disconnects the line for valve pin closing from the air supply but due to its special construction at the same time couples it with an additional supply line which is permanently pressurised. By doing this the valve pin is actively kept in closed position. Combined with the decreased temperature in the nozzle a further protruding of plastic material into the cavity is prevented. The operating units for the valves are positioned sideways in the mould plate and are easily accessible while the mould is mounted on the machine. Of course it would also be possible to shut off a cavity by uninstalling the valve pin and decreasing the nozzle temperature. This is easily possible for all EWIKON single drive units but would require to take the mold off the machine. Furthermore, when processing materials with a tendency to drool such as TPE a decrease of the nozzle temperature alone is not sufficient to prevent plastic material from leaking out of the gate. Here the new technology with active closing of the gate offers enhanced reliability.

Up to now the new technology has been integrated into five 24+24-drop two-component moulds for a customer from the cosmetics industry who processes TPE as soft component.
The EWIKON application engineering department is the centre of the global service network and employs seven service technicians at the headquarters in Frankenberg and further three abroad at international subsidiaries. Their tasks include pre-production tests of customer moulds, material trials with EWIKON test moulds, fault analysis as well as of course a quick on-site support for domestic and international customers, ranging from assistance for system installation and mould start-up to troubleshooting and maintenance work.

In the course of the last production area extension in Frankenberg the EWIKON technical centre has been completely redesigned and considerably enlarged. With a total of 400 m² the space available could be more than doubled. Two new crane systems allow to handle loads up to 2.5 tons. The technical centre is equipped with three injection moulding machines, one of them for two-component moulding with clamping forces reaching from 500 to 1600 Mpa and for shot weights up to 250 grams. An additional injection moulding machine for smallest shot weights will shortly complete the machinery. Furthermore, a new meeting area has been incorporated.

In direct proximity to the technical centre lies an area for special tasks where two experienced toolmakers are responsible for the prototype and test mould production, the preparation of moulds for material tests as well as for the assembly and maintenance of particularly complex hot halves. To enable an autarkic production with high flexibility the technical equipment includes a brand new 5-axis milling centre, conventional turning technology and a cylindrical grinding machine.